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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,513	09/19/2003	Ann Marie Schmidt	55873-C	2104
7590	02/10/2005		EXAMINER ANDRES, JANET L	
John P. White Cooper & Dunham LLP 1185 Avenue of the Americas New York, NY 10036			ART UNIT 1646	PAPER NUMBER

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/666,513

**Applicant(s)**

SCHMIDT ET AL.

**Examiner**

Janet L. Andres

**Art Unit**

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2 and 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **RESPONSE TO AMENDMENT**

1. Applicant's amendment filed 22 November 2004 is acknowledged. Claims 2 and 15 are pending and under examination in this office action. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

#### ***Claim Rejections/Objections Withdrawn***

2. The objection to the specification is withdrawn in response to Applicant's amendment.

3. The rejection of claims 1 and 15 under 35 U.S.C. 112, first paragraph, as lacking written description is withdrawn in response to Applicant's cancellation of claim 1 and amendment to claim 15.

4. The rejection of claims 1, 2, and 15 under 35 U.S.C. 112, second paragraph, as indefinite in the recitation of EN-RAGE and in the reference to a table is withdrawn in response to Applicant's cancellation of claim 1 and amendment to claims 2 and 15.

5. The rejection of claims 1 and 2 under 35 U.S.C. 102(b) is withdrawn in response to Applicant's cancellation of claim 1 and arguments with respect to claim 2.

#### ***Claim Rejections Maintained/New Grounds of Rejection***

6. The rejection of claim 15 under 35 U.S.C. 102(b) as anticipated by EP 0 731 166 A2 and U.S. 5,986,832 is maintained for reasons of record in the office action of 24 August 2004.

Applicant argues that EP 0 731 166 A2 and U.S. 5,986,832 do not teach SEQ ID NO: 2.

Applicant's argument is correct, but claim 15 is drawn to a sequence comprising a fragment of SEQ ID NO: 2. The sequence taught in EP 0 731 166 A2 and U.S. 5,986,832 comprises a fragment of SEQ ID NO: 2, since it is identical in several regions. It is noted that

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“comprises a fragment” would also encompass any protein, since any amino acid would be a fragment of SEQ ID NO: 2.

7. The rejection of claim 2 under 35 U.S.C. 101 as claiming the same invention as 10/665867 is maintained for reasons of record in the previous office action. Applicant has not traversed this rejection and it is thus maintained of record.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 15 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 15 of U.S. Patent No. 10/665867. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 15 is drawn to the single embodiment of EN-RAGE taught in 10/665867.

9. Claims 2 and 15 are newly rejected under 35 U.S.C. 112, second paragraph, as indefinite in the phrase “having (or “has”) the N-terminal amino acid sequence show in SEQ ID NO: 2”. It is not clear whether Applicant intends “N-terminal amino acid sequence” to refer to SEQ ID NO: 2 in its entirety, or to an N-terminal portion thereof.

NO CLAIM IS ALLOWED.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday, Tuesday, Thursday, Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.  
8 February 2005

  
JANET ANDRES  
PRIMARY EXAMINER